

December 22, 2003

Dockets Management Branch (HFA-305)
Attention Docket Numbers 02N-0276; 02N-0278
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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RE: Registration of Food Facilities and Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Interim Final Rules

To Whom It May Concern:

The National Paint and Coatings Association (NPCA)¹ is pleased to submit the following comments concerning the Interim Final Rules for the Registration of Food Facilities and Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (hereinafter referred to as the "Interim Rules").² NPCA member companies have a long history of consistent supply of high quality, safe, reliable and effective food contact coatings and believe that the U.S. Food and Drug Administration's (FDA) revised definition of "food" in the Interim Rules is a permissible interpretation that appropriately reflects the Congressional intent of the underlying legislation. NPCA appreciates the opportunity to reiterate our comments in this regard during the current comment period.

FDA's Proposed Rules³ under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (hereinafter referred to as the "Act"), relied on the definition of "food" under the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 201(f) of the FFDCA defines food to include substances that migrate into food from food packaging and other articles that contact food. Thus, food packaging and other food contact materials were expressly included as examples of food in the proposed definitions, with the result that, under the rules as proposed, facilities that manufacture/process, pack, or hold food packaging, food-contact materials, or their components would have been required to register and to comply with the prior notice regulations. NPCA, as well as other commenters, noted that this definition was unduly broad and did not correspond to the intent of the Act. After considerable analysis FDA has revised the definition of food in the Interim Rules to exclude food contact substances as defined by the FFDCA. NPCA supports this decision.

¹ NPCA is a voluntary, nonprofit trade association representing some 400 manufacturers of paints, coatings, adhesives, sealants, and caulks, raw materials suppliers to the industry, and product distributors. As the preeminent organization representing the coatings industry in the United States, NPCA's primary role is to serve as ally and advocate on legislative, regulatory and judicial issues at the federal, state, and local levels. In addition, NPCA provides members with such services as research and technical information, statistical management information, legal guidance, and community service project support.

² 68 Fed. Reg. 58894 and 58974 (October 10, 2003).

³ 68 Fed. Reg. 5378 and 5428 (February 3, 2003).

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The Interim Rules state that FDA has determined it is permissible, for purposes of the registration and prior notice provisions, to exclude food contact materials from the definition of food. Food contact substances is then defined using Section 49(h)(6) of the FFDCA, which states that “food contact substance means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.” NPCA believes this is a permissible construction of the term food under the Department of Health and Human Service’s (hereinafter referred to as the “Department”) authority to promulgate regulations under the FFDCA as well as FDA’s mandate under the Act to issue regulations in an expedited time period for the protection of the US food supply.⁴

The Department’s authority to promulgate regulations under the FFDCA encompasses “regulations for the efficient enforcement” of the FFDCA. FDA’s mandate under the Act is to develop “crisis communications and education strategy with respect to bioterrorist threats to the *food supply* (emphasis added).” FDA’s reasoned determination in the Interim Rules that the definition of food does not include food contact materials provides for the efficient enforcement of the regulations by restricting the new requirements under the Act to processing and manufacturing facilities truly in the food business. This approach also corresponds to the legislative intent of the Act. Instead of diluting FDA’s resources by requiring a vast amount of food contact industries to comply with the regulations, FDA will now be better positioned to ensure the goals of the Act – the prompt response to threats on the US food supply.

While FDA requests comment on only a specific set of issues under the Interim Rule for Registration, and states in both the Registration and Prior Notice Interim Rules that comments will not taken that have previously been considered during the rulemakings, FDA requests comment on the entire Interim Rule for Prior Notice. Thus, NPCA reiterates the need for FDA to balance the regulatory burden on industry of regulations under the Act with the need for registering, tracking and monitoring all industries associated with the food industry. For the reasons previously stated and reiterated above, NPCA believes that the definition of “food” under the Interim Rules appropriately strikes this balance and urges FDA to retain the provision excluding food contact materials from the definition of food in the final regulations under the Act. Requiring coatings and food packaging manufacturing facilities to register and provide prior notification of imports unnecessarily burdens industry without commensurate benefit to the intention of the Act – deterring and responding to terrorism of US food supply.

Sincerely,



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⁴ See 21 USC §371(a) and PL 107-188 Title III, Subtitle A, respectively.